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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No .	Applicant(s)
	09/915,181	EDWARDS ET AL.
	Examiner Ram R. Shukla	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 11 January 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-66 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-66 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

1. Claims 1-66 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT1 by detecting the expression of VGLUT1 at nucleic acid level, classified in class 435, subclass 6.
- IV. Claims 1, 11, and 16, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT1 by detecting the expression of VGLUT1 at protein level, classified in class 435, subclass 7.1.
- VII. Claims 1, 12 and 17, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT1 by measuring the activity of VGLUT1, classified in class 435, subclass 4.
- X. Claims 24-26, 29, 30-32 and 35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by directly contacting a nucleic acid encoding VGLUT1 receptor to the agent in vitro and detecting the binding of the agent to the VGLUT1 nucleic acid, classified in class 435, subclass 388.21.
- XIII. Claims 24-26 and 33-35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by directly contacting a VGLUT1 receptor polypeptide to the agent and detecting the binding of the agent to the VGLUT1 polypeptide, classified in class 435, subclass 388.22.
- XVI. Claims 24-26, 29, 30-32 and 35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by contacting a cell comprising a nucleic acid encoding VGLUT1 receptor

to the agent ex vivo and detecting the binding of the agent to the VGLUT1 nucleic acid, classified in class 435, subclass 7.2.

XIX. Claims 24-26 and 33-35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by contacting a cell comprising a nucleic acid encoding VGLUT1 receptor to the agent ex vivo and detecting the binding of the agent to the VGLUT1 polypeptide, classified in class 435, subclass 7.8.

XXII. Claims 38-50, drawn to a host cell comprising a nucleic acid encoding VGLUT1 receptor, a kit comprising the cell and a method of increasing glutamate transport in a cell by expression of VGLUT1, classified in class 435, subclass 325.

XXV. Claims 51-60, drawn to a knockout mammal comprising a disruption in endogenous VGLUT1 glutamate receptor, classified in class 800, subclass 8.

SET-II

II. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT2 by detecting the expression of VGLUT2 at nucleic acid level, classified in class 435, subclass 6.

V. Claims 1, 11 and 16, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT2 by detecting the expression of VGLUT2 at protein acid level, classified in class 435, subclass 7.1.

VIII. Claims 1, 12 and 17, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT2 by measuring the activity of VGLUT2, classified in class 435, subclass 4.

- XI. Claims 24-26, 29, 30-32 and 35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by directly contacting a nucleic acid encoding VGLUT2 receptor to the agent in vitro and detecting the binding of the agent to the VGLUT2 nucleic acid, classified in class 435, subclass 388.21.
- XIV. Claims 24-26 and 33-35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by directly contacting a VGLUT2 receptor polypeptide to the agent and detecting the binding of the agent to the VGLUT2 polypeptide, classified in class 435, subclass 388.22.
- XVII. Claims 24-26, 29, 30-32 and 35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by contacting a cell comprising a nucleic acid encoding VGLUT2 receptor to the agent ex vivo and detecting the binding of the agent to the VGLUT2 nucleic acid, classified in class 435, subclass 7.2.
- XX. Claims 24-26 and 33-35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by contacting a cell comprising a nucleic acid encoding VGLUT2 receptor to the agent ex vivo and detecting the binding of the agent to the VGLUT2 polypeptide, classified in class 435, subclass 7.8.
- XXIII. Claims 38-50, drawn to a host cell comprising a nucleic acid encoding VGLUT2 receptor, a kit comprising the cell and a method of increasing glutamate transport in a cell by expression of VGLUT2, classified in class 435, subclass 325.
- XXVI. Claims 51-60, drawn to a knockout mammal comprising a disruption in endogenous VGLUT1 glutamate receptor, classified in class 800, subclass 8.

SET-III

- III. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell

comprising a nucleic acid encoding VGLUT3 by detecting the expression of VGLUT3 at nucleic acid level, classified in class 435, subclass 6.

- VI. Claims 1, 11 and 16, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT3 by detecting the expression of VGLUT3 at protein level, classified in class 435, subclass 7.1.
- IX. Claims 1, 12 and 17, drawn to a method of screening for an agent that modulates uptake of glutamate into a cell comprising a nucleic acid encoding VGLUT3 by measuring the activity of VGLUT3, classified in class 435, subclass 4.
- XII. Claims 24-26, 29, 30-32 and 35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by directly contacting a nucleic acid encoding VGLUT3 receptor to the agent *in vitro* and detecting the binding of the agent to the VGLUT3 nucleic acid, classified in class 435, subclass 388.21.
- XV. Claims 24-26 and 33-35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by directly contacting a VGLUT3 receptor polypeptide to the agent and detecting the binding of the agent to the VGLUT2 polypeptide, classified in class 435, subclass 388.22.
- XVIII. Claims 24-26, 29, 30-32 and 35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by contacting a cell comprising a nucleic acid encoding VGLUT3 receptor to the agent *ex vivo* and detecting the binding of the agent to the VGLUT3 nucleic acid, classified in class 435, subclass 7.2.
- XXI. Claims 24-26 and 33-35, drawn to a method of prescreening for a potential modulator of glutamate transporter activity by contacting a cell comprising a nucleic acid encoding VGLUT3 receptor to the agent *ex vivo* and detecting the binding of the agent to the VGLUT3 polypeptide, classified in class 435, subclass 7.8.

XXIV. Claims 38-50, drawn to a host cell comprising a nucleic acid encoding VGLUT3 receptor, a kit comprising the cell and a method of increasing glutamate transport in a cell by expression of VGLUT3, classified in class 435, subclass 325.

XXVII. Claims 51-60, drawn to a knockout mammal comprising a disruption in endogenous VGLUT1 glutamate receptor, classified in class 800, subclass 8.

SET-IV

XXVIII. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of increasing or inhibiting glutamate uptake in a cell comprising contacting a cell with an agent that inhibits or increases the expression or activity of a VGLUT polypeptide, wherein said agent is an antisense molecule, classified in class 514, subclass 44.

XXIX. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of increasing or inhibiting glutamate uptake in a cell comprising contacting a cell with an agent that inhibits or increases the expression or activity of a VGLUT polypeptide, wherein said agent is a ribozyme molecule, classified in class 514, subclass 44.

XXX. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of increasing or inhibiting glutamate uptake in a cell comprising contacting a cell with an agent that inhibits or increases the expression or activity of a VGLUT polypeptide, wherein said agent is a catalytic DNA molecule, classified in class 514, subclass 44.

XXXI. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of increasing or inhibiting glutamate uptake in a cell comprising contacting a cell with an agent that inhibits or increases the expression or activity of a

VGLUT polypeptide, wherein said agent is an anti-VGLUT antibody, classified in class 514, subclass 2.

XXXII. Claims 1-10, 13-15, 18-23, 38-47, drawn to a method of increasing or inhibiting glutamate uptake in a cell comprising contacting a cell with an agent that inhibits or increases the expression or activity of a VGLUT polypeptide, wherein said agent is a nucleic acid that disrupts a VGLUT gene by homologous recombination, classified in class 514, subclass 44.

3. Inventions I, IV, VII, X, XIII, XVI, and XIX of set I are patentably distinct each from the other because they have different modes of operation, different functions, or different effects. In the instant case the different inventions are drawn to methods of identifying agents and the methods use distinct steps and steps of one method are not mutually exclusive with the steps of the other method. In other words, steps of one method cannot be used to practice the other methods. For example, the method of group I requires detection of nucleic acid, the method of group VII requires measurement of the activity of a receptor, the method of group X requires binding and detection of agent-protein binding in vitro, the method of group XVIII requires binding of the agent to a polypeptide in vitro and detection of the complex, the method of group XVI requires the binding of the agent to the nucleic acid in a cell and detection of the complex, and the method of group XIX requires the binding of the agent to a polypeptide in a cell and detection of the complex respectively. It is noted that these methods steps are specific to each method and therefore, the search for each of the claimed methods will not be mutually exclusive and an independent search will be required for each group.

Inventions of the group XXII and groups I, IV, VII, XVI and XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the host cells of the group XXII are used in the methods of groups I, IV, VII, XVI and XIX.

Invention of group XXV is patentably distinct from the inventions of each of the groups I, IV, VII, X, XIII, XVI, XIX and XXII of set I because they have different modes of operation, different functions, or different effects. In the instant case the invention of group XXV is drawn to a transgenic mammal in which gene encoding VGLUT1 receptor has been disrupted. The methods of the groups I, IV, VII, X, XIII, XVI, XIX and XXII can not be used to make the transgenic mammal of group XXV and the transgenic mammal of groups XXV can not be used to practice the methods of groups I, IV, VII, X, XIII, XVI, XIX and XXII.

4. It is noted that the methods of the groups II, V, VIII, XI, XIV, XVII and XX of the set II are patentably distinct each from the other because they have different modes of operation, different functions, or different effects. In the instant case the different inventions are drawn to methods of identifying agents and the methods use distinct steps and steps of one method are not mutually exclusive with the steps of the other method, for reasons discussed above in paragraph 3 in reference to groups I, IV, VII, X, XIII, XVI, and XIX.

Inventions of the group XXIII and groups II, V, VIII, XI, XIV, XVII and XX of set II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the host cells of the group XXIII are used in the methods of groups II, V, VIII, XI, XIV, XVII and XX.

Invention of group XXVI is patentably distinct from the inventions of each of the groups II, V, VIII, XI, XIV, XVII and XX of set II because they have different modes of operation, different functions, or different effects. In the instant case the invention of group XXVI is drawn to a transgenic mammal in which gene encoding VGLUT2 receptor has been disrupted. The methods of the groups II, V, VIII, XI, XIV, XVII and XX cannot be used to make the transgenic mammal of group XXVI

and the transgenic mammal of groups XXV cannot be used to practice the methods of groups II, V, VIII, XI, XIV, XVII and XX.

5. It is noted that the methods of the groups III, VI, IX, XII, XV, XVIII and XXI of the set III are patentably distinct each from the other because they have different modes of operation, different functions, or different effects. In the instant case the different inventions are drawn to methods of identifying agents and the methods use distinct steps and steps of one method are not mutually exclusive with the steps of the other method, for reasons discussed above in paragraphs 3 and 4 in reference to groups I, IV, VII, X, XIII, XVI, and XIX and II, V, VIII, XI, XIV, XVII and XX respectively.

Inventions of the group XXIV and groups III, VI, IX, XII, XV, XVIII and XXI of set III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the host cells of the group XXIII are used in the methods of groups III, VI, IX, XII, XV, XVIII and XXI.

Invention of group XXVII is patentably distinct from the inventions of each of the groups III, VI, IX, XII, XV, XVIII and XXI of set II because they have different modes of operation, different functions, or different effects. In the instant case the invention of group XXVII is drawn to a transgenic mammal in which gene encoding VGLUT3 receptor has been disrupted. The methods of the groups III, VI, IX, XII, XV, XVIII and XXI cannot be used to make the transgenic mammal of group XXVII and the transgenic mammal of groups XXV cannot be used to practice the methods of groups III, VI, IX, XII, XV, XVIII and XXI.

6. The methods of the groups XXVIII-XXXII are patentably distinct each from the other because they use different reactants, the reactants of one group can not be used in the method of the other group, and the structure and steps of one group can not be used in other methods. For example, the structure of an

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antisense molecule is different from that of a ribozyme or catalytic DNA or an antibody or a nucleic acid that disrupts a gene by homologous recombination. Additionally, the search for an antisense molecule will not be coextensive with the search for a ribozyme or catalytic DNA or antibody or nucleic acid for homologous recombination. Additionally, the steps of a method using an antibody will be different from those used in a method using ribozyme or a method of disrupting a gene. Therefore, the methods of the groups XXVIII-XXXII are patentably distinct and will require separate search consideration.

7. The inventions of the sets I -IV are patentably distinct each from the other because they are drawn to methods and products using nucleic acids that have distinct structure (VGLUT1, VGLUT2 and VGLUT3) and will have different function and/or encode different proteins with different amino acid structure. Additionally, the nucleic acid encoding the receptor of set I will not encode the protein of set II or of III and vice versa. Likewise the methods of set IV cannot be used to make the products of groups I-III or for practicing the methods of groups I-III. Furthermore, search for the nucleic acids or proteins of the three sets are not co-extensive.

8. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and/or their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be

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accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

When amending claims, applicants are advised to submit a clean version of each amended claim (without underlining and bracketing) according to **§ 1.121(c)**. For instructions, Applicants are referred to

<http://www.uspto.gov/web/offices/dcom/olia/aipa/index.htm>.

Applicants are also requested to submit a copy of all the pending/under consideration claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Tiffany N. Tabb whose telephone number is (703) 605-1238.

Ram R. Shukla, Ph.D.



RAM R. SHUKLA, PH.D
PATENT EXAMINER